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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/774,814	01/30/2001	Olivier Ballevre	112701-136	2493

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EXAMINER	
LIU, SAMUEL W	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 01/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/774,814	BALLEVRE ET AL.	
	Examiner	Art Unit	
	Samuel W Liu	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18,20-28,32-36,38-41,43,44 and 50-55* is/are pending in the application.

4a) Of the above claim(s) *45-49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18,20-28,32-36,38-41,43,44 and 50-55* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The response filed 20 October 2003, which adds claims 50-55, cancels claims 19, 29-31, 37, 42, and amends claims 1-2, 8, 15, 20-21, 24-25, 38 and 43 has been entered. The pending claims 1-18, 20-28, 32-36, 38-41, 43-44 and 50-55 are under examination to the extent that they are drawn to the elected invention.

Note that claims 45-49 are drawn to a process of reducing oxidative stress. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Note that the grounds of objection and/or rejection not explicitly stated and/or set forth below are withdrawn.

The previous rejection under 35 USC 102(e) is withdrawn in light of the applicants' amendment to the claims.

Claim Rejections - 35 USC §103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-18, 28, 32-36, 38-41, 43-44 and 50-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hennebicq-Reig *et al.* (*Biochem. J.* (1998) 334, 283-295) taken with Bertolo, R. F. P. *et al.* (*J. Nutr.* (1998) 128, 1752-1759), Demichele, S. J. (US Pat. No. 6468987), Pearson, G. R. et al. (*Vet. Record* (1987) 121, 557-559), and Granados, R. R. *et al.* (US Pat No. 6187558).

Hennebicq-Reig *et al.* teach importance of threonine for mucin synthesis (see Table 4), suggesting that threonine is the most critical amino acid (accounting for ~ 25% total amino acid residues in polypeptide portion of mucin glyco-protein) and that increasing threonine amount is proportional to enhancing or/and maintaining mucin biosynthesis. The Hennebicq-Reig *et al.* teaching is applied to claims 1, 8, 14, 28, 32, 35 and 40 of the current application.

Bertolo et al. teach that administering threonine is necessary for maintenance of gut mucous coating as threonine requirement is proportional to mucin production, wherein mucin comprises large amount of threonine, i.e., accounted for > 40% of the amino acid residues of total polypeptide of mucin, (see the second paragraph of the left column, page 1758).

Bertolo *et al.* teach that threonine is an essential amino acid for growing gut (see the right column, page 1758), wherein *production of mucin protein is proportional to threonine requirement* (see the second paragraph, page 1758), and wherein nearly 90% metabolizing threonine is incorporated into gastric mucosal protein, *i.e.*, mucin, equivalent to 61% of dietary threonine is metabolized in gastrointestinal gust (see the paragraphs at the bridging pages 1757-1758), strongly suggesting that threonine is a key component for mucin synthesis, and for maintaining or/and increase mucin synthesis, as applied to the application claims 8, 14-15, 28, 32, 38, 42-43 and 50.

Bertolo *et al.* teach a process of administering total parenteral nutrition (TPN) that contains all the required nutrients including protein, threonine and other amino acids, fat, carbohydrates, vitamins, and minerals to a patient by employing the indicator amino acid oxidation technique, and that the TPN solution has the recommended threonine contents (see

Materials and Methods section, the third paragraph). The Bertolo *et al.* teachings are applied to claims 3, 9-10, 16-17, 36, 41 and 44 of the current application.

Bertolo *et al.* teach that daily recommended threonine for a patient is 0.4-0.5 g/kg(body weight)·day (see page 1757, the left column, lines 5-8) while the experimental dada show threonine requirement is about 0.58 g/kg·day (see page 1756, the right column, the 2nd paragraph). Thus, Bertolo et al. teach that the amount of threonine compresses at least 110% of the daily-recommended amount of threonine (i.e., 0.58/ 0.50 ≈ 110%), as applied to the application claims 32-34.

Further, Bertolo et al. teach the plasma threonine concentration after administering the composition comprising threonine is 1732 μM (see page 1755, the left column, the 2nd paragraph), i.e., 1.7 mM, which meets the limitation set forth in the application claims 51-55.

Demichele *et al.* teach a method for treating ulcerative colitis (an intestinal inflammatory disease may caused by bacterial infection to intestinal mucosa) comprising administering to a patient a nutritional composition comprising a source of protein (see patent claim 29-33 and item *d* of patent claim 14). Also, Demichele *et al.* teach that the administered composition comprising protein source contains 75% whey protein (see column 17, line 54) and the protein is hydrolyzed (see the patent claim 19). Since whey protein contains ~ 7.4% of threonine by total weight of amino acid residues *as is evidenced by the specification* at page 5, line 28-29, the threonine content would be 75% × 7.4% ≈ 5.6 %, which is applied to the limitations set forth in claims 1, 3-4, 15-17, 35-36, 38-41 and 43-44 of the current application.

Since it is a factual indicia that mucosal change is associated with colitis ulceration (*an intestinal inflammation* disease state) in an animal, i.e., an altered mucin level is proportional to mucosal damage, i.e., ulceration, as taught by Pearson et al. (see "discussion" section), suggesting association of mucin alteration with ulceration disease state, i.e., the above Demichele *et al.* teaching is applicable to the application claims 1 and 35.

Also, Demichele *et al.* teach the nutritional composition comprises lipid source and carbohydrate (see the patent claim 14, items *a* and *b*) and the composition comprising 10-50% medium chain triglycerides and 25-80% fish oil which is enriched in *Omega*-3 fatty acids that belongs to long chain triglyceride (see the patent claim 14), the Demichele *et al.* teaching thus is applied to claims 5-7, 11-13 and 18 of the instant application.

Further, Demichele *et al.* also teach that the protein source of the administered nutritional composition provides about 21.0% energy (calories) (see Table 6), as applied to the application claim 50.

Demichele *et al.* teaching with respect to a process of treating intestinal bacterial infection in a patient comprising administering to the patient threonine-rich composition is further supported by Granados et al. reference. Granados *et al.* teach the protective function of mucin in intestinal mucosal layer, and that mucin plays an active role in preventing bacterial infection of digestive tract (see column 1, lines 17-21 and 54-67). Additionally, Granados *et al.* teach that mucin is rich in threonine indicating threonine is a key component of mucin (see column 4, lines 42-52). The above Demichele et al. and Granados et al. teaching are applied to claims 40-44.

One of ordinary skill in the art would have combined the teachings of Hennebicq-Reig *et al.* and Bertolo et al., because the teachings with respect to (*a*) threonine playing an essential role in maintaining mucin protein synthesis as taught by Hennebicq-Reig *et al.*, and (*b*) route and amount of administering threonine or/and nutrition composition comprising threonine as taught by Bertolo et al., would have led the skilled artisan to successfully arriving at the invention, i.e., a process of maintaining or/and increasing the synthesis of mucin in a patient.

Also, it would have been obvious for the skilled artisan to combine the teachings of Hennebicq-Reig et al., Demichele et al., Pearson, G. R. et al. and Granados et al., because (i) Hennebicq-Reig et al. teach that threonine is one of the most important nutritional building blocks of mucin, (ii) Demichele et al. teach that the nutrition has a significant impact on mucosal glycoprotein synthesis, which comprises threonine-rich proteins, (*e.g.*, *whey* protein), lipids and carbohydrates, and teach a method of treating an intestinal inflammatory disease, i.e., ulcerative colitis which is associated with alteration of mucin synthesis as taught by Pearson et al., comprising administering to a patient a nutritional composition having protein(s) that comprises rich threonine content (e.g., whey protein); and, the Demichele et al. teaching is also applicable to the method of treating bacterial infection comprising same because Granados et al. explicitly teach that mucin plays an active role in preventing microbial infection of gastric mucosal layer (see column 1, lines 17-22, and column 4, lines 42-43).

When combined, the skilled artisan would have administered sufficient amount of threonine or threonine-rich nutritional composition (as taught by Demichele et al.) to a subject for treating disease states associated with an alteration of mucin level, e.g., intestinal inflammation or bacterial infection. When combined, there would have been the following

advantages: (*a*) the formulated nutrition can also be applied to young patients, as taught by Demichele *et al.* (see column 2, lines 61-65), (*b*) threonine can be readily formulated with proteins, *e.g.*, whey protein, and other nutritional components, e.g., fatty acid and carbohydrate as taught by Demichele et al. (see the statement *supra*); and (*c*) Bertolo et al. teaching provides analytic assessment for administering threonine in consideration of excess amount threonine might cause toxic effect on the patient (see page 1752 and abstract).

Therefore, the skilled artesian would have been motivated to combine the above reference teachings to develop method(s) of maintaining or/and increasing mucin synthesis, or/and treating disease states, e.g., intestinal bacterial infection or/and the bacterial infection associated gastric inflammation in a patient *via* administering a composition comprising threonine or/and threonine-rich nutritional supplement (*e.g.*, whey protein). Thus, the claimed invention was *prima facie* obvious to make and use at the time it was made.

Applicants' response to the rejection under 35 USC 103(a)

The response filed 20 October 2003 commends that Hennebicq-Reig et al. only teach that threonine is a significant component of mucin glycoprotein but fails to suggest the importance of threonine for mucin synthesis, and asserts that the Hennebicq-Reig reference is deficient with respect to the claimed invention (see page 13, the 3rd paragraph). The applicants' argument is unpersuasive because the applicants' comment and assertion are contradictory to each other, and because the reference does teach the impotence of threonine for mucin biosynthesis which is provided by the factual evidence shown in Table 4 of the reference where indicates that threonine accounts for at least 25 % (the highest percent of the listed amino acids). One of

ordinary skill in the art when the invention is made would readily recognize the critical role threonine in mucin synthesis.

The response argues that Demichele et al. patent does not applied to the current rejection because the Demichele's method of treating intestinal inflammation comprising administering the nutritional composition to the patient is the different mechanism than that disclosed by the current application (see pages 10-11 and page 13, the last paragraph). Applicants' argument is found unpersuasive because Demichele et al. teach said method of administering the patient a composition comprising threonine rich composition (see the patent claims 14, item *d*, claim 29, Table 11, and column 17, lines 54) e.g., whey protein the accounts for about 5.6% threonine content (see also above rejection). Applicants also assert that Table 12 of Demichele's reference shows threonine is 4.43% instead of 5.6 % of total protein (see page 11, 3rd paragraph). It is of note that although Demichele et al. teach both the percentage of threonine amount in total protein, Demichele et al. especially emphasize that the nutritional product in Table 14 of the invention comprises 75% whey protein (see item 15 of Table 14 components), which contains 5.6% threonine (w/w). Moreover, the instant application claims appear to include whey protein (*threonine-rich* polypeptide) as the composition for increasing or/and maintaining mucin synthesis or/and treating the disease states mentioned above (see claims 3, 16-17, 22, 26, 39 and 44).

Applicants assert that the recited reference in combination fail to suggest the importance of threonine for mucin synthesis, and Hennebicq-Reig et al. reference on its own is deficient in teaching same (see page 13). Contrary to the applicants' argument, Hennebicq-Reig et al. has clearly suggested that threonine is the most important amino acid component by providing

factual evidence that threonine counts the highest percentage among all the amino acids listed in Table 4. Thus, applicant's argument is not persuasive.

The response argues that the Granados at al. reference relates to inveterate mucin which is not applicable to the current invention (see page 13, the last paragraph). The applicants' argument is found unpersuasive because the mucin protein as recited in the claims of the current application is neither defined in the specification nor the claims in regard to where the mucin is isolated from. The Granados et al. teaching is thus applicable to the claims mentioned in the above rejection.

Also, the response argues that the Pearson et al. reference does not qualify as prior art on the basis of merely suggesting that damage to the protective mucus layer is associated with intestinal inflammation (see the last paragraph on page 13). The comment is unpersuasive because Note that Pearson at el. teaches that mucosal change is associated with colitis ulceration (*an intestinal inflammation* disease state) in an animal, i.e., an altered mucin level is proportional to mucosal damage, i.e., ulceration. Thus, applicants' assertion is incorrect.

Further, the response asserts Bertolo et al. reference only suggest a connection between a decrease threonine requirement and gut atrophy and gastrointestinal mucosa requires high amount threonine content because threonine is a critical amino acid for the synthesis of mucin at the surface of the intestine. Thus, applicant's argument that Bertolo et al. reference cannot be employed as an obviousness prior art in combination with the Hennebicq-Reig et al. reference (see page 14) is unpersuasive because Hennebicq-Reig *et al.*, teach or/and suggest a critical role in *maintaining* or/and *increasing* mucin (glyco-protein) synthesis since the mucin synthesis is proportional to threonine amount, and Bertolo et al. teach the route and amount of administering

to the patient threonine or/and nutrition composition comprising threonine. When combined the above tow reference teachings, the skilled artisan would have been led to successfully arriving at the invention, i.e., a process of maintaining or/and increasing the synthesis of mucin in a patient in need, which are directly applicable to claims 8-10, 14-17, 28, 32-34 and 51-53 (see the above rejection under 35 USC 103).

Provisional Rejection, 35 U.S.C. 101, Double Patenting

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 14, 28, 32, 33 and 34 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 14, 28, 32, 33 and 34 of application No.10182854, respectively. This is a provisional double patenting rejection since the conflicting claims have

not in fact been patented. Claim 14 of application 10182854 is word to word identical to claim 14 of the instant application.

The claims of the instant application and claims of the application 10182854 disclose the identical subject matter, *i.e.*, a method of increasing the synthesis of mucins in a patient comprising supplement a diet of the patient by adding threonine to the said diet (see claim 28), and a method of increasing increasing the synthesis of mucins in a patient comprising administering to the patient a composition comprising threonine that is at least 30% of daily recommended amount of threonine (see claims 32-34).

Claim Rejections - Provisional Rejection, Obviousness Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b). Effective 1 January 1994, a registered attorney or agent of

record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 20-28 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-18 of Application No.10182854. This is a provisional double patenting rejection because the conflicting claims have not in fact been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows:

Claims 1-18 of instant application have been fully disclosed in their equivalents claims 1-18 of Application No. 10182854, respectively. Claims 1-7 of application 10182854 discloses a method of treating a disease comprising administering a composition to a subject a protein source comprising threonine that is at least 5.5% (w/w) of total *amino acids*. The current application claims 1-7 set forth a method comprising the same except that threonine comprises 5.5% (w/w) of *protein source*. Because the protein source encompasses amino acids, the claims 1-7 of the current application and application 10182854 are obvious variations. Claims 8-13 of application 10182854 disclose a method of producing a nutritional composition for maintaining the synthesis of mucins in a patient comprising using a protein source comprising threonine that is at least 5.5% (w/w) of the amino acids. Claims 8-13 of the instant application sets forth a method of maintaining the synthesis of mucins in a patient comprising administering to the patient a composition comprising a protein source wherein threonine is at least 5.5% (w/w) of said protein source. Because (i) the claims of instant application and the claims of 10182854 are

directed to the common subject matter, i.e., maintaining mucin synthesis, which is inherent in the process of providing or producing threonine-rich composition, and (ii) all the limitations set forth in the dependent claims 9-13 for 10182854 and the current application are identical, the claims of 10182854 and the instant application are obvious variation.

Claims 14-18 of application 10182854 and claims 14-18 of the current application are obvious variation as well. The independent claim 14 for both applications are identical except that 10182854 claim 15 sets forth that threonine comprises at least 5.5% (w/w) of *amino acids* of the protein source in comparison to that the application claim 15 recites that threonine comprises at least 5.5% (w/w) of the *protein source*, wherein the protein source includes milk protein, whey protein and glycoprotein *etc.* (see page 5 of the specification of the instant application). Since the protein source encompasses the amino acids, 10182854 discloses the common subject matter as that of the current application.

Claim 20 of application 10182854 sets forth a method of treating a disease state comprising administering to a patient a nutritional composition that has a protein source comprising threonine which is at least 7.5% (w/w) of amino acids; claim 20 of the instant application disclose the same but threonine amount in the claimed composition is 7.4% (w/w) of the protein source. Since 7.4% is an obvious variation of 7.5%, the claim of 10182854 and the claim of the current application are obvious variation from each other.

Claims 21-23 of the current application and 10182854 are identical except for claim 21 recitation "14% (w/w) of the *protein source*" (the instant application) in comparison with the recitation of claim 21 "14% (w/w) of the *amino acids*" (application 10182854). Since the protein

source encompasses the amino acids, application 10182854 discloses the common subject matter of that of the instant application.

Claim 24 of application 10182854 sets forth a method of maintaining mucin synthesis comprising administering to a patient a nutritional composition comprising threonine that is at least 7.4 (w/w) of the acids; claim 20 of the instant application disclose the same but threonine amount in the composition is 7.4% (w/w) of the protein source. Because, in application 10182854, claim 24 is obviously directed to amino acids in view of the specification thereof (see page 5) (herein, amino acids are regarded as species of a genus of biological acid), the claim 24 of the current application and 10182854 are obvious variation.

Claims 25-27 of the current application and 10182854 are identical except for the claim 25 recitation of 10182854 "14% (w/w) of the amino acids" in comparison with the claim 25 recitation of the instant application "14% (w/w) of the *protein source*". Since the protein source encompasses the amino acids, the claims of these two applications are obvious variation.

Application No. 10182854 claims the same subject matter as the instant application although they are different in scope of the claims compared. Thus, the claims of application 10182854 and the claims of current application are obvious variation.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel Wei Liu whose telephone number is (703) 306-3483. The examiner can normally be reached from 9:00 a.m. to 5:30 p.m. on weekdays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher

Low, can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is 703 308-4242 or 703 872-9306 (official) or 703 872-9307 (after final). Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703 305-4700.

SWL

Samuel Wei Liu, Ph.D.

December 10, 2003

ROBERT A. WAX
PRIMARY EXAMINER